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510(k) Summary

SEP 30 2010

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Submitter Name and Address:	Given Imaging Ltd. Hermon Building New Industrial Park PO Box 258 Yoqneam 20692 Israel Tel.: 011-972-4-9097730 Fax: 011-972-4-9938060
Contact Person:	Tim Thomas RAC Vice President Regulatory Affairs & Quality Assurance Email: tim.thomas@givenimaging.com
Phone Number:	770-662-0870 ext. 1006
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Establishment Registration Number:	9710107
Date Prepared:	April 27, 2010
Device Trade Name(s):	PillCam® Express™ Video Capsule Delivery Device
Device Common Name:	Ingestible telemetric gastrointestinal capsule imaging system & Endoscope and/or accessories
Classification:	Regulation No: 21 CFR 876.1300 & 876.1500 Class: II Review panel - Gastroenterology/Urology NEZ – System, Imaging, Gastrointestinal, Wireless, Capsule and KOG - Endoscope and/or accessories
Predicate Device(s):	Capsule endoscopy delivery device (K040494)

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General Device Description:	The PillCam® Express Capsule Endoscopy Delivery System is comprised of three parts: ▪ Catheter ▪ Syringe ▪ Capsule holder The catheter is passed through the accessory channel of a standard endoscope and the capsule holder is snapped on to the distal end of the device. The endoscope is used to guide the Capsule Endoscopy Delivery System to the proximal duodenum. The capsule is then released pneumatically, using an air-filled syringe attached to the proximal end of the catheter. Once the capsule is deployed, the endoscope is withdrawn and the capsule holder is cut off at the distal part of the device with scissors. The catheter is then retracted and discarded. The PillCam® Express Capsule Endoscopy Delivery System is a single-use, disposable and latex-free product.
Intended Use:	Indications for Use: The disposable PillCam® Express™ video capsule delivery device is indicated for the transendoscopic delivery of the PillCam® SB video capsule in patients age 8 and above who are either unable to ingest the PillCam capsule or are known to have slow gastric emptying time
Technological Characteristics:	The technology characteristics are similar as the predicate device.
Performance Data:	Performance data demonstrating safety and effectiveness of the PillCam® Express™ video capsule delivery device was obtained from non-clinical bench testing and from a clinical validation study. The non-clinical bench testing included strength testing of the cup to the catheter, force to release the capsule, force to maintain the capsule in the cup, and strength of the catheter. The clinical validation study included twenty five patients in the age range of 22-89 years old. All capsules were successfully placed into the duodenum and no serious adverse events were reported in the clinical study.
Conclusion:	Based on the technological characteristics and clinical performance of the device, Given Imaging Ltd. believes that

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Given PillCam® Express™ video capsule delivery device and the predicate capsule delivery device selected are substantially equivalent and do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Tim Thomas
VP Regulatory Affairs and Quality Assurance
Given Imaging Limited
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SEP 30 2010

Re: K101200
Trade/Device Name: PillCam® Express™ Video Capsule Delivery Device
Regulation Number: 21 CFR §876.1300
Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system
Regulatory Class: II
Product Code: NEZ
Dated: September 20, 2010
Received: September 21, 2010

Dear Mr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K101200

Device Name: PillCam® Express™ Video Capsule Delivery Device

SEP 30 2010

Indications for Use:

The disposable PillCam® Express™ video capsule delivery device is indicated for the transendoscopic delivery of the PillCam® SB video capsule in patients age 8 and above who are either unable to ingest the PillCam capsule or are known to have slow gastric emptying time.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101200